IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC GLOBAL HOLDING SA, ALEMBIC PHARMACEUTICALS, INC., CRYSTAL PHARMACEUTICAL (SUZHOU) CO., LTD., MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED, MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, VIATRIS INC., NANJING NORATECH PHARMACEUTICAL CO., LIMITED, Defendants.	C.A. No. _____

COMPLAINT

Novartis Pharmaceuticals Corporation ("Novartis"), by its attorneys, hereby alleges as follows:

NATURE OF THE ACTION

1. This is a patent infringement action arising under Title 35 of the United States Code and concerning Abbreviated New Drug Applications ("ANDAs") submitted to the United States Food and Drug Administration ("FDA") by the above-named Defendants seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of sacubitril/valsartan tablets, generic versions of Novartis's ENTRESTO® tablets, 24 mg/26 mg,

49 mg/51 mg, and 97 mg/103 mg, prior to the expiration of U.S. Patent No. 11,096,918 (the "'918 patent").

PARTIES

A. Novartis

2. Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business in East Hanover, New Jersey.

B. Defendants

a. Alembic Pharmaceuticals Limited; Alembic Global Holding SA; Alembic Pharmaceuticals, Inc. (ANDA No. 213682)

3. On information and belief, Alembic Pharmaceuticals Limited is a corporation organized and existing under the laws of India, having a principal place of business at Alembic Road, Vadodara, Gujarat, India 390003.

4. On information and belief, Alembic Global Holding SA is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Rue Fritz-Courvoisier 40, 2300 La Chaux-de-Fonds, Switzerland. On information and belief, Alembic Global Holding SA is a wholly owned subsidiary of Alembic Pharmaceuticals Limited.

5. On information and belief, Alembic Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a registered agent for the service of process at National Registered Agents, Inc., 160 Greentree Drive, Suite 101, Dover, Delaware 19904, and having a principal place of business at 750 Route 202, Bridgewater, New Jersey 08807. On information and belief, Alembic Pharmaceuticals, Inc. is a wholly owned subsidiary of Alembic Global Holding SA.

6. On information and belief, Alembic Pharmaceuticals Limited develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

7. On information and belief, Alembic Global Holding SA develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

8. On information and belief, Alembic Pharmaceuticals, Inc., manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

9. On information and belief, Alembic Pharmaceuticals Limited has submitted to the FDA ANDA No. 213682 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Alembic ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Alembic ANDA Products in or into the United States, including Delaware, prior to the expiration of the '918 patent.

10. Alembic Pharmaceuticals Limited has committed an act of infringement in this judicial district by filing ANDA No. 213682 with the intent to make, use, sell, offer for sale, and/or import the Alembic ANDA Products in or into this judicial district, prior to the expiration of the '918 patent, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

11. On information and belief, Alembic Global Holding SA acted in concert with and under the direction of Alembic Pharmaceuticals Limited, and acted in concert with and directed Alembic Pharmaceuticals, Inc., in the preparation and submission of ANDA No. 213682, and, if the ANDA is approved, will act in concert with and under the direction of Alembic

Pharmaceuticals Limited, and will act in concert with and direct Alembic Pharmaceuticals, Inc., to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Alembic ANDA Products in or into the United States, including Delaware, prior to the expiration of the ’918 patent.

12. On information and belief, Alembic Pharmaceuticals, Inc. acted in concert with and under the direction of Alembic Pharmaceuticals Limited and/or Alembic Global Holding SA in the preparation and submission of ANDA No. 213682, and, if the ANDA is approved, will act in concert with and under the direction of Alembic Pharmaceuticals Limited and/or Alembic Global Holding SA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Alembic ANDA Products in or into the United States, including Delaware, prior to the expiration of the ’918 patent.

13. Alembic Pharmaceuticals Limited, by itself or together with Alembic Global Holding SA and/or Alembic Pharmaceuticals, Inc., has taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Alembic ANDA Products, that will be purposefully directed at Delaware and elsewhere.

14. On information and belief, Alembic Pharmaceuticals Limited has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware either directly or indirectly through subsidiaries, agents, or affiliates, including Alembic Pharmaceuticals, Inc.; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

15. Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. have availed themselves of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *CyDex Pharm. Inc. v. Alembic Global Holding SA et al.*, C.A. No. 19-956 (D. Del.); *Otsuka Pharm. Co., Ltd. et al. v. Alembic Pharm. Ltd. et al.*, C.A. No. 19-2007 (D. Del.); *Astrazeneca AB et al. v. Alembic Pharm. Ltd. et al.*, C.A. No. 20-202 (D. Del.); *Abbvie Inc. et al. v. Alembic Pharm. Ltd. et al.*, C.A. No. 20-968; *Otsuka Pharm. Co., Ltd. et al. v. Alembic Pharm. Ltd. et al.*, C.A. No. 20-1365; *Novartis Pharm. Corp. v. Alembic Pharm. Ltd. et al.*, C.A. No. 20-74 (D. Del.).

16. Alembic Pharmaceuticals Limited, the entity that, on information and belief, submitted ANDA No. 213682, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213682 in the District of Delaware, and has agreed, only for the purposes of such action(s), not to challenge personal jurisdiction and venue in the District of Delaware.

b. Crystal Pharmaceutical (Suzhou) Co., Ltd. (ANDA No. 213605)

17. On information and belief, Crystal Pharmaceutical (Suzhou) Co., Ltd. ("Crystal") is a corporation organized and existing under the laws of China, having a principal place of business at B4-101, Biological Nano Park, No. 218, Xinghu Street, Suzhou Industrial Park, China.

18. On information and belief, Crystal develops, manufactures, distributes, sells, and/or imports drugs for the entire United States market and does business in every state including Delaware, either directly or indirectly.

19. On information and belief, Crystal has submitted to the FDA ANDA No. 213605 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Crystal ANDA

Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Crystal ANDA Products in or into the United States, including Delaware, prior to the expiration of the '918 patent.

20. Crystal has committed an act of infringement in this judicial district by filing ANDA No. 213605 with the intent to make, use, sell, offer for sale, and/or import the Crystal ANDA Products in or into this judicial district, prior to the expiration of the '918 patent, an act of infringement that has led and will lead to foreseeable harm and injury to Plaintiff Novartis, a Delaware corporation.

21. Crystal has taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Crystal ANDA Products, that will be purposefully directed at Delaware and elsewhere.

22. On information and belief, Crystal has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

23. Crystal has availed itself of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Novartis Pharm. Corp. v. Alkem Labs. Ltd. et al.*, C.A. No. 19-1979 (D. Del.); *Neurocrine Biosciences, Inc. v. Crystal Pharm. (Suzhou) Co., Ltd.*, C.A. No. 21-1464 (D. Del.); *Novartis Pharm. Corp. v. Crystal Pharm. (Suzhou) Co., Ltd.*, C.A. No. 21-1452 (D. Del.).

24. Crystal, the entity that, on information and belief, submitted ANDA No. 213605, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213605 in the District of Delaware, and has agreed, only for the purposes of such action(s), not to challenge personal jurisdiction and venue in the District of Delaware.

c. MSN Pharmaceuticals Inc.; MSN Laboratories Private Limited; MSN Life Sciences Private Limited (ANDA No. 213748)

25. On information and belief, MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having a registered agent for the service of process at United States Corporation Agents, Inc., 300 Delaware Avenue, Suite 210-A, Wilmington, Delaware 19801, and having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854. On information and belief, MSN Pharmaceuticals Inc. is a wholly owned subsidiary of and U.S. agent for MSN Laboratories Private Limited.

26. On information and belief, MSN Laboratories Private Limited is a corporation organized and existing under the laws of India, having a principal place of business at MSN House, C-24, Sanathnagar Industrial Estate, Hyderabad, 500018, Telangana, India.

27. On information and belief, MSN Life Sciences Private Limited is a corporation organized and existing under the laws of India, having a principal place of business at Sy No - 21/A & 21AA, Mambapur (Village), Gummadidala (Mandal), Sangareddy (District) - 502313, Telangana, India. On information and belief, MSN Life Sciences Private Limited is a wholly owned subsidiary of MSN Laboratories Private Limited.

28. On information and belief, MSN Pharmaceuticals Inc. develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

29. On information and belief, MSN Laboratories Private Limited develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

30. On information and belief, MSN Life Sciences Private Limited develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

31. On information and belief, MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited have submitted to the FDA ANDA No. 213748 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("MSN ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the MSN ANDA Products in or into the United States, including Delaware, prior to the expiration of the '918 patent.

32. MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited have committed an act of infringement in this judicial district by filing ANDA No. 213748 with the intent to make, use, sell, offer for sale, and/or import the MSN ANDA Products in or into this judicial district, prior to the expiration of the '918 patent, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

33. On information and belief, MSN Pharmaceuticals Inc. acted in concert with and under the direction of MSN Laboratories Private Limited, and acted in concert with MSN Life Sciences Private Limited, in the preparation and submission of ANDA No. 213748, and, if the ANDA is approved, will act in concert with and under the direction of MSN Laboratories Private Limited, and will act in concert with MSN Life Sciences Private Limited, to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the MSN ANDA

Products in or into the United States, including Delaware, prior to the expiration of the ’918 patent.

34. On information and belief, MSN Life Sciences Private Limited acted in concert with and under the direction of MSN Laboratories Private Limited, and acted in concert with MSN Pharmaceuticals Inc., in the preparation and submission of ANDA No. 213748, and, if the ANDA is approved, will act in concert with and under the direction of MSN Laboratories Private Limited, and will act in concert with MSN Pharmaceuticals Inc., to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the MSN ANDA Products in or into the United States, including Delaware, prior to the expiration of the ’918 patent.

35. MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited, by themselves or together with MSN Life Sciences Private Limited, have taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the MSN ANDA Products, that will be purposefully directed at Delaware and elsewhere.

36. On information and belief, MSN Laboratories Private Limited has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates, including MSN Pharmaceuticals Inc.; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

37. On information and belief, MSN Life Sciences Private Limited has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug

products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates, including MSN Pharmaceuticals Inc.; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

38. MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited have availed themselves of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Vanda Pharm. v. MSN Pharm. Inc. et al.*, C.A. No. 19-926 (D. Del.), *Novartis Pharm. Corp. v. Dr. Reddy's Labs., Inc. et al.*, C.A. No. 19-2053 (D. Del.), *Exelixis, Inc. v. MSN Labs. Private Ltd. et al.*, C.A. No. 20-633 (D. Del.).

39. MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited, the entities that, on information and belief, submitted ANDA No. 213748, have agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213748 in the District of Delaware, and have agreed, only for the purposes of such action(s), not to challenge personal jurisdiction and venue in the District of Delaware.

d. Mylan Pharmaceuticals Inc.; Mylan Laboratories Limited; Viatris Inc. (collectively, the "Mylan Defendants") (ANDA No. 213646)

40. On information and belief, Mylan Pharmaceuticals Inc. is a corporation organized under the laws of the State of West Virginia, purporting to have a principal place of business at 3711 Collins Ferry Road, Morgantown, West Virginia 26505. On information and belief, Mylan Pharmaceuticals Inc. is an agent, affiliate, wholly owned subsidiary and alter ego of Viatris Inc., and subsumed within Viatris Inc.

41. On information and belief, Mylan Laboratories Limited is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 564/A122, Road No. 92, Jubilee Hills, Hyderabad 500034, India. On information and belief, Mylan Laboratories Limited is a wholly owned subsidiary of Viatris Inc., and an agent and affiliate of Mylan Pharmaceuticals Inc. and Viatris Inc.

42. On information and belief, Viatris Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1000 Mylan Blvd., Canonsburg, Pennsylvania, 15317.

43. On information and belief, Viatris Inc.'s website states that "Viatris was formed in 2020 through the combination of Mylan and Upjohn, a legacy division of Pfizer. By integrating the strengths of these two companies, including our approximately 37,000 colleagues globally, we aim to deliver increased access to affordable, quality medicines for patients worldwide. Our global portfolio includes . . . generics, including branded and complex generics . . . . We are headquartered in the United States . . . . As we work to fully transition to the Viatris brand commercially and operationally around the world, you may continue to see both the Mylan and Upjohn names in certain markets." (https://www.viatris.com/en/about-us/our-story (last visited October 24, 2022)).

44. On information and belief, any corporate separateness that existed between Viatris Inc. and Mylan Pharmaceuticals Inc. shortly after Viatris Inc. was formed has dissolved, and Mylan Pharmaceuticals Inc. is now no more than an alter ego for Viatris Inc.

45. On information and belief, Viatris Inc. is working to fully transition the Viatris brand commercially and operationally around the world, and as a result, Viatris Inc. has been methodically divesting Mylan Pharmaceuticals Inc. properties, assuming corporate

responsibilities of Mylan Pharmaceuticals Inc., adopting employees of Mylan Pharmaceuticals Inc., commingling funds with Mylan Pharmaceuticals Inc., and subsuming Mylan Pharmaceuticals Inc. into Viatris Inc. For example, on information and belief, as of March 7, 2022, Viatris Inc. closed Mylan Pharmaceuticals Inc.'s facility located at 781 Chestnut Ridge Road, Morgantown, West Virginia, 26505 and auctioned off its equipment. (*See, e.g.*, https://www.wboy.com/news/local/monongalia-and-preston/former-mylan-viatris-facility-auctions-off-equipment/ (last visited October 24, 2022); https://www.hgpauction.com/auctions/110662/viatris-morgantown-2/ (last visited October 24, 2022)). On information and belief, on March 31, 2022, West Virginia University took ownership of 781 Chestnut Ridge Road, Morgantown, West Virginia, 26505. (*See, e.g.*, https://www.wdtv.com/2022/03/31/wvu-purchases-former-mylan-plant/ (last visited October 24, 2022)). On information and belief, Viatris Inc. sold this property to West Virginia University. (*Id.*)

46. On information and belief, Robert J. Coury, formerly the executive chairman of Mylan, is now the executive chairman of Viatris Inc. following the completion of the $27 billion combination of Mylan with Pfizer's Upjohn business to create Viatris Inc. (https://www.viatris.com/en/about-us/our-leaders/robert-j-coury (last visited on October 24, 2022)). On information and belief, Mr. Coury "leads the [Viatris Inc.] board of directors, oversees the strategic direction of the company in collaboration with executive management, and advises the management team as they execute on the company's strategy to drive value creation . . ." (*Id.*)

47. On information and belief, Viatris Inc. shares with or has subsumed one or more corporate officers and employees of Mylan Pharmaceuticals Inc. (*See, e.g.*,

https://www.fiercepharma.com/pharma/mylan-crowns-former-ceo-coury-as-executive-chairman-as-upjohn-merger-deal-faces-delays (last visited October 24, 2022); https://www.viatris.com/en/about-us/our-leaders (last visited October 24, 2022); https://www.wsj.com/market-data/quotes/VTRS/company-people/executive-profile/268055 (last visited October 24, 2022); https://www.sec.gov/Archives/edgar/data/1792044/000119312521313437/d163117ddef14a.htm (last visited October 24, 2022)). On information and belief, Viatris Inc.'s sharing or subsuming of Mylan Pharmaceuticals Inc.'s corporate officers and employees demonstrates that Mylan Pharmaceuticals Inc. is an alter ego of and subsumed within Viatris Inc.

48. On information and belief, the shared or subsumed officers of Mylan Pharmaceuticals Inc. maintain their offices at the same place of business as Viatris Inc.'s principal place of business at 1000 Mylan Blvd., Canonsburg, Pennsylvania, 15317. (*See, e.g.*, https://www.sec.gov/Archives/edgar/data/1792044/000119312521313437/d163117ddef14a.htm (last visited October 24, 2022)). On information and belief, Viatris Inc.'s and Mylan Pharmaceuticals Inc.'s use of the same office or business location demonstrates that Mylan Pharmaceuticals Inc. is an alter ego of and subsumed within Viatris Inc.

49. On information and belief, upon the combination of Mylan and Upjohn, Viatris Inc. assumed certain retention agreements and retirement benefit agreements between Mylan and certain of its officers. (*See, e.g.*, https://www.sec.gov/Archives/edgar/data/1792044/000119312521313437/d163117ddef14a.htm (last visited October 24, 2022)).

50. On information and belief, Mylan Pharmaceuticals Inc. holds itself out to the public as "Mylan Pharmaceuticals Inc., a Viatris company." (*See, e.g.*,

https://newsroom.viatris.com/2022-01-18-Mylan-Pharmaceuticals-Inc-,-a-Viatris-Company,-Conducting-Voluntary-Recall-of-One-Batch-of-Semglee-R-insulin-glargine-injection-,-100-units-mL-U-100-,-3-mL-Prefilled-Pens,-Due-to-the-Potential-for-a-Missing-Label-in-the-Batch (last visited October 24, 2022)). On information and belief, Mylan Pharmaceuticals Inc.'s holding itself out as Viatris Inc. demonstrates that Mylan Pharmaceuticals Inc. is an alter ego of and subsumed within Viatris Inc.

51. On information and belief, as Mylan entities, including Mylan Pharmaceuticals Inc., are now part of Viatris Inc., attempts to access Mylan's website, mylan.com, result in a pop-up window redirecting access to Viatris Inc., along with a statement that: "Mylan is now part of Viatris, a new global healthcare company committed to empowering people to live healthier at every stage of life." (https://www.mylan.com (last visited October 24, 2022)). On information and belief, Mylan's LinkedIn website states: "Follow us on our new journey as Viatris. www.linkedin.com/company/viatris" and "We have combined with Upjohn, a legacy division of Pfizer, and are now Viatris. Follow along on our new journey as we empower people worldwide to live healthier at every stage of life. www.linkedin.com/company/viatris." (https://www.linkedin.com/company/mylan/ (last visited October 24, 2022)). On information and belief, the redirection from mylan.com to the website of Viatris Inc. and Mylan's holding itself out as Viatris Inc. demonstrates that Mylan Pharmaceuticals Inc. is an alter ego of and subsumed within Viatris Inc.

52. On information and belief, Mylan employees are now identified as Viatris Inc. employees. (*See, e.g.*, (https://www.linkedin.com/in/brandon-mcmahon-2754a263/ (last visited October 24, 2022)). On information and belief, the identification of Mylan employees as Viatris

Inc. employees demonstrates that Mylan Pharmaceuticals Inc. is an alter ego of and subsumed within Viatris Inc.

53. On information and belief, current job listings for Mylan Pharmaceuticals Inc. indicate employment is with Viatris Inc., demonstrating that Mylan Pharmaceuticals Inc. is an alter ego of and subsumed within Viatris Inc. (*See, e.g.*, https://www.indeed.com/jobs?q=Mylan%20Pharmaceuticals%20Inc.&l=Morgantown%2C%20WV&from=mobRdr&utm_source=%2Fm%2F&utm_medium=redir&utm_campaign=dt&vjk=8203d5b1e393f80f (last visited October 24, 2022)). On information and belief, the identification of jobs associated with Mylan Pharmaceuticals Inc. as being with Viatris Inc. demonstrates that Mylan Pharmaceuticals Inc. is an alter ego of and subsumed within Viatris Inc.

54. On information and belief, on July 1, 2021, Viatris Inc. entered into a $4.0 billion revolving facility agreement with certain lenders (the "2021 Revolving Facility.") (*See* Viatris Inc. Form 10-K, dated Mar. 1, 2021 (https://www.sec.gov/ix?doc=/Archives/edgar/data/0001792044/000179204421000009/vtrs-20201231.htm (last visited October 24, 2022)). On information and belief, Mylan Pharmaceuticals Inc. has access to the 2021 Revolving Facility. (*Id.*) On information and belief, Viatris Inc. and Mylan Pharmaceuticals Inc. operate as a single entity with the capacity to borrow funds from revolving loan accounts that Viatris Inc. has instituted with certain lenders.

55. On information and belief, Viatris Inc. entered into a two-year $400 million "Receivables Facility" agreement in 2020 which expired in April 2022. (*Id.*) Mylan Pharmaceuticals Inc. "has access to $400 million under the Receivables Facility." (*Id.*) On information and belief, under Viatris Inc.'s Receivables Facility agreement, Mylan Pharmaceuticals Inc., operating as a single entity with Viatris Inc., has the capacity to sell its

accounts receivables to Viatris Inc.'s subsidiary Mylan Securitization LLC for the purpose of accessing instant funds from outstanding unpaid invoices. (*Id*.) On information and belief, Viatris Inc. thereby funds Mylan Pharmaceuticals Inc. through Viatris Inc.'s subsidiary Mylan Securitization LLC. On information and belief, Viatris Inc. and Mylan Pharmaceuticals Inc.'s joint use of the 2021 Revolving Facility and 2020 Receivables Facility demonstrates the commingling of funds and that Mylan Pharmaceuticals Inc. is an alter ego of and subsumed within Viatris Inc.

56. On information and belief, Viatris Inc. agreed to pay $264 million in settlement fees, to resolve class action cases pending in the U.S. District Court for the District of Kansas on behalf of defendants Mylan N.V., Mylan Specialty L.P., Mylan Pharmaceuticals Inc., and Heather Bresch. (*See* Viatris Inc. Form 10-Q, dated May 9, 2022 (https://www.sec.gov/ix?doc=/Archives/edgar/data/0001792044/000179204422000017/vtrs-20220331.htm (last visited October 24, 2022))); *In Re: EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litigation*, MDL No. 2785, 17-md-2785-DDC-TJJ (D. Kan. March 11, 2022).) On information and belief, Viatris Inc.'s payment of debt incurred by itself and its subsidiaries demonstrates a commingling of funds between Viatris Inc. and its subsidiaries including Mylan Pharmaceuticals Inc., a lack of corporate separateness, and the various Mylan subsidiaries, including Mylan Pharmaceuticals Inc., being subsumed within Viatris Inc.

57. On information and belief, Viatris Inc.'s 2021 10-K report states that references to "Viatris" therein refer to "Viatris Inc. and its subsidiaries." (Viatris Inc. Form 10-K, dated Mar. 1, 2021 (https://www.sec.gov/ix?doc=/Archives/edgar/data/0001792044/000179204422000010/vtrs-

20211231.htm (last visited October 24, 2022))). Viatris Inc.'s 2021 10-K report identifies Mylan Pharmaceuticals Inc. as a Viatris Inc. subsidiary, and references the "Viatris Charter." (*Id.*) Upon information and belief, the "Viatris Charter" is the "amended and restated certificate of incorporation of Viatris Inc." According to Viatris Inc.'s 2021 10-K report, the Viatris Charter designates Delaware "as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by Viatris' stockholders, which could discourage lawsuits against Viatris and its directors and officers . . . . To the fullest extent permitted by law, this exclusive forum provision will apply to state and federal law claims, including claims under the federal securities laws . . . . This exclusive forum provision may limit the ability of Viatris' stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with Viatris or its directors or officers, which may discourage such lawsuits against Viatris or its directors or officers." (*Id.*)

58. On information and belief, Viatris Inc. refers to FDA approvals of ANDAs submitted by Mylan Pharmaceuticals Inc. as Viatris Inc.'s FDA ANDA approvals. (*See, e.g.*, (*See, e.g.*, *Mylan Launches First Generic Restasis. (RX/Generic Drugs),* CHAIN DRUG REV., Feb. 21, 2022, at 31 ("Rajiv Malik, president of [Mylan Pharmaceuticals Inc.'s] parent company, Viatris Inc., said: 'I am pleased that Viatris has received the first FDA approval for generic Restasis . . . .'" and "Viatris developed markets president Tony Mauro said: 'The approval of generic Restasis reinforces our ongoing commitment to deliver innovative solutions . . . . We look forward to quickly bringing this important product to millions of Americans . . . .'" (https://mydigitalpublication.com/publication/?i=738336&article_id=4212714&view=articleBrowser (last visited October 24, 2022)); *Viatris Inc. Announces Receipt of the First FDA Approval for Generic Version of Symbicort® Inhalation Aerosol, Breyna™ (Budesonide and Formoterol*

Fumarate Dihydrate Inhalation Aerosol), in Partnership with Kindeva ("Viatris President Rajiv Malik added: 'The momentous FDA final approval of Breyna is further evidence of our well-established development expertise and proven ability to move up the value chain with more complex products by leveraging our robust scientific capabilities to target gaps in healthcare and patient needs. This approval also builds on our past successes of bringing other complex products first to market and demonstrates the continued delivery of our strong pipeline.'") (https://newsroom.viatris.com/2022-03-16-Viatris-Inc-Announces-Receipt-of-the-First-FDA-Approval-for-Generic-Version-of-Symbicort-R-Inhalation-Aerosol,-Breyna-TM-Budesonide-and-Formoterol-Fumarate-Dihydrate-Inhalation-Aerosol-,-in-Partnership-with-Kindeva (Mar. 16, 2022) (last visited October 24, 2022).)

59. On information and belief, products identified as products of "Mylan Pharmaceuticals Inc." or "Mylan Pharmaceuticals Inc., a Viatris Company" by the FDA are now identified as products of Viatris Inc. on Viatris Inc.'s website. (*Compare e.g.*, FDA Listing of Authorized Generics as of Oct. 1, 2022 (https://www.fda.gov/media/77725/download (last visited October 24, 2022)) and Viatris Inc.'s Product Catalog (https://www.viatris.com/en-us/lm/countryhome/us-products/productcatalog/ (last visited October 24, 2022))).

60. On information and belief, Viatris Inc.'s 2021 10-K report refers to Viatris Inc. and its subsidiaries as "the Company" and identifies Mylan Pharmaceuticals Inc. as a "wholly owned subsidiary." (Viatris Inc. Form 10-K, dated Mar. 1, 2021 (https://www.sec.gov/ix?doc=/Archives/edgar/data/0001792044/000179204422000010/vtrs-20211231.htm (last visited October 24, 2022))). According to the report, "Viatris invests significant sums in R&D and in manufacturing capacity. [Viatris] also often incur[s] substantial litigation expense as a result of defending or challenging brand patents or exclusivities . . . " (*Id.*)

Viatris Inc.'s 2021 10-K report further states that "[t]he Company is involved in a number of patent litigation lawsuits involving the validity and/or infringement of patents held by branded pharmaceutical manufacturers including but not limited to the matters described below. The Company uses its business judgement to decide to market and sell certain products, in each case based on its belief that the applicable patents are invalid and/or that its products do not infringe, notwithstanding the fact that allegations of patent infringement(s) or other potential third party rights have not been finally resolved by the courts." (*Id.*) Following this statement, Viatris Inc. identifies multiple Hatch-Waxman litigations in which Mylan Pharmaceuticals Inc. is involved. (*Id.*)

61. On information and belief, Mylan Pharmaceuticals Inc. acting as an alter ego of Viatris Inc. develops, manufactures, distributes, sells and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

62. On information and belief, Mylan Laboratories Limited develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

63. On information and belief, including, based on, *inter alia*, the Mylan Defendants' website, publicly-available SEC 10-K filings, and publicly-available press releases, the Mylan Defendants hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including Delaware.

64. On information and belief, the Mylan Defendants act in concert, with Mylan Pharmaceuticals Inc. and Viatris acting as a single enterprise, with respect to the preparation,

submission, approval and maintenance of ANDAs, including ANDAs as filed and amendments thereto. On information and belief, Mylan Pharmaceuticals Inc., acting as an alter ego of Viatris Inc., has submitted to the FDA ANDA No. 213646 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Mylan ANDA Products"), including amendments seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Mylan ANDA Products in or into the United States, including Delaware, prior to the expiration of the '918 patent.

65. Mylan Pharmaceuticals Inc., acting as an alter ego of Viatris Inc., has committed an act of infringement in this judicial district by filing ANDA No. 213646, including amendments, with the intent to make, use, sell, offer for sale, and/or import the Mylan ANDA Products in or into this judicial district, prior to the expiration of the '918 patent, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis.

66. On information and belief, the Mylan Defendants acted in concert, with Mylan Pharmaceuticals Inc. and Viatris Inc. acting as a single enterprise, in the preparation and submission of ANDA No. 213646, including amendments, and, if the ANDA is approved, will continue to act in concert, with Mylan Pharmaceuticals Inc. and Viatris Inc. acting as a single enterprise, to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Mylan ANDA Products in or into the United States, including Delaware, prior to the expiration of the '918 patent.

67. The Mylan Defendants, acting in concert, with Mylan Pharmaceuticals Inc. and Viatris Inc. acting as a single enterprise, have taken the costly, significant step of applying to the FDA for approval, including submission of ANDA No. 213646 as filed and amendments thereto,

to engage in future activities, including the marketing of the Mylan ANDA Products, that will be purposefully directed at Delaware and elsewhere.

68. On information and belief, Mylan Pharmaceuticals Inc., acting as an alter ego of Viatris Inc., has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

69. On information and belief, Mylan Laboratories Limited has systematic and continuous contacts with Delaware, has established distribution channels for drug products in Delaware, regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

70. On information and belief, Viatris Inc. has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

e. Nanjing Noratech Pharmaceutical Co., Limited (ANDA No. 213671)

71. On information and belief, Nanjing Noratech Pharmaceutical Co., Limited ("Noratech") is a corporation organized and existing under the laws of China, having a principal place of business at 6/F, Building F6, No. 9 Weidi Road, Jiangsu Life Science and Technology Innovation Park, Qixia District, Nanjing, China.

72. On information and belief, Noratech develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

73. On information and belief, Noratech has submitted to the FDA ANDA No. 213671 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Noratech ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Noratech ANDA Products in or into the United States, including Delaware, prior to the expiration of the '918 patent.

74. Noratech has committed an act of infringement in this judicial district by filing ANDA No. 213671 with the intent to make, use, sell, offer for sale, and/or import the Noratech ANDA Products in or into this judicial district, prior to the expiration of the '918 patent, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

75. Noratech has taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Noratech ANDA Products, that will be purposefully directed at Delaware and elsewhere.

76. On information and belief, Noratech has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and

continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

77. Noratech, the entity that, on information and belief, submitted ANDA No. 213671, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213671 in the District of Delaware, and has agreed, only for the purposes of such action(s), not to challenge personal jurisdiction and venue in the District of Delaware.

JURISDICTION AND VENUE

78. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

a. Alembic Pharmaceuticals Limited; Alembic Global Holding SA; Alembic Pharmaceuticals, Inc.
(ANDA No. 213682)

79. This Court has personal jurisdiction over Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. because, on information and belief, each such Defendant has committed or has aided, abetted, contributed to, or participated in the commission of tortious acts of patent infringement in preparing and submitting ANDA No. 213682 with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which acts have led to foreseeable harm and injury to Novartis, a Delaware corporation.

80. This Court also has personal jurisdiction over Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. because, on information and belief, each such Defendant, upon approval of ANDA No. 213682, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA

No. 213682 that will be purposefully directed at Delaware, including the marketing of the Alembic ANDA Products in Delaware, prior to the expiration of the '918 patent.

81. This Court also has personal jurisdiction over Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. because, on information and belief, each such Defendant's affiliations with the State of Delaware, including Alembic Pharmaceuticals, Inc.'s incorporation in Delaware, and Alembic Pharmaceuticals Limited's and Alembic Global Holding SA's ownership of and actions in concert with Alembic Pharmaceuticals, Inc., are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum.

82. This Court also has personal jurisdiction over Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. because each such Defendant has availed itself of the legal protections of the State of Delaware, by admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

83. Alembic Pharmaceuticals Limited, the entity that, on information and belief, submitted ANDA No. 213682, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213682 in the District of Delaware, and has agreed, only for the purposes of such action(s), not to challenge personal jurisdiction and venue in the District of Delaware.

84. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc.

85. Venue is proper in this Court because Alembic Pharmaceuticals, Inc. is incorporated in the State of Delaware and therefore resides in this judicial district, and because

Alembic Pharmaceuticals Limited and Alembic Global Holding SA are foreign entities who may be sued in any judicial district, including Delaware. 28 U.S.C. § 1400(b); 28 U.S.C. § 1391(c)(3).

b. Crystal Pharmaceutical (Suzhou) Co., Ltd. (ANDA No. 213605)

86. This Court has personal jurisdiction over Crystal because Crystal has committed tortious acts of patent infringement in preparing and submitting ANDA No. 213605 with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which acts have led to foreseeable harm and injury to Plaintiff Novartis, a Delaware corporation.

87. This Court also has personal jurisdiction over Crystal because, on information and belief, Crystal, upon approval of ANDA No. 213605, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213605 that will be purposefully directed at Delaware, including the marketing of the Crystal ANDA Products in Delaware, prior to the expiration of the ’918 patent.

88. This Court also has personal jurisdiction over Crystal because, on information and belief, Crystal’s affiliations with the State of Delaware are sufficiently continuous and systematic as to render Crystal essentially at home in this forum.

89. Crystal, the entity that, on information and belief, submitted ANDA No. 213605, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213605 in the District of Delaware and not to contest personal jurisdiction or venue in the District of Delaware in such an action.

90. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Crystal.

91. Venue is proper in this Court because Crystal is a foreign entity who may be sued in any judicial district, including the District of Delaware. 28 U.S.C. § 1391(c)(3).

c. MSN Pharmaceuticals Inc.; MSN Laboratories Private Limited; MSN Life Sciences Private Limited (ANDA No. 213748)

92. This Court has personal jurisdiction over MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited because, on information and belief, each such Defendant has committed or has aided, abetted, contributed to, or participated in the commission of tortious acts of patent infringement in preparing and submitting ANDA No. 213748 with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which acts have led to foreseeable harm and injury to Novartis, a Delaware corporation.

93. This Court also has personal jurisdiction over MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited because, on information and belief, each such Defendant, upon approval of ANDA No. 213748, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213748 that will be purposefully directed at Delaware, including the marketing of the MSN ANDA Products in Delaware, prior to the expiration of the ’918 patent.

94. This Court also has personal jurisdiction over MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited because each such Defendant’s affiliations with the State of Delaware, including MSN Pharmaceuticals Inc.’s incorporation in Delaware, MSN Laboratories Private Limited’s ownership of and actions in concert with MSN Pharmaceuticals Inc., and MSN Life Sciences Private Limited’s actions in concert with MSN Pharmaceuticals Inc. are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum.

95. This Court also has personal jurisdiction over MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited because each such Defendant has availed itself of the legal

protections of the State of Delaware, by admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

96. MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited, the entities that, on information and belief, submitted ANDA No. 213748, have agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213748 in the District of Delaware, and have agreed, only for the purposes of such action(s), not to challenge personal jurisdiction and venue in the District of Delaware.

97. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited.

98. Venue is proper in this Court because MSN Pharmaceuticals Inc. is incorporated in the State of Delaware and therefore resides in this judicial district, and because MSN Laboratories Private Limited and MSN Life Sciences Private Limited are foreign entities who may be sued in any judicial district, including Delaware. 28 U.S.C. § 1400(b); 28 U.S.C. § 1391(c)(3).

d. Mylan Pharmaceuticals Inc.; Mylan Laboratories Limited; Viatris Inc. (collectively, the "Mylan Defendants") (ANDA No. 213646)

99. This Court has personal jurisdiction over the Mylan Defendants because, on information and belief, the Mylan Defendants, acting in concert, with Mylan Pharmaceuticals Inc. and Viatris Inc. acting as a single enterprise, have committed and/or have aided, abetted, contributed to, or participated in the commission of tortious acts of patent infringement in preparing and submitting ANDA No. 213646 with a certification pursuant to 21 U.S.C. §

355(j)(2)(A)(vii)(IV), including its amendments, which acts have led to foreseeable harm and injury to Novartis, a Delaware corporation.

100. This Court also has personal jurisdiction over the Mylan Defendants because, on information and belief, the Mylan Defendants, acting in concert, with Mylan Pharmaceuticals Inc. and Viatris Inc. acting as a single enterprise, upon approval of ANDA No. 213646, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213646 that will be purposefully directed at Delaware, including the marketing of the Mylan ANDA Products in Delaware, prior to the expiration of the '918 patent.

101. This Court also has personal jurisdiction over the Mylan Defendants because, on information and belief, each such Defendant's affiliations with the State of Delaware, including Viatris Inc.'s incorporation in Delaware, Viatris Inc.'s ownership of and actions in concert and as a single enterprise with Mylan Pharmaceuticals Inc., Viatris Inc.'s ownership of and actions in concert with Mylan Laboratories Limited, are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum.

102. On information and belief, it would be unfair not to impute Viatris Inc.'s residency to Mylan Pharmaceuticals Inc. as the alter ego of Viatris Inc. when Viatris Inc. has so dominated and subsumed Mylan Pharmaceuticals Inc. into Viatris Inc.

103. Venue is proper in this Court because Viatris Inc. is incorporated in the State of Delaware and therefore resides in this judicial district, because Viatris Inc.'s Delaware residence should be imputed to Mylan Pharmaceuticals Inc. as an alter ego of Viatris Inc. due to a lack of corporate separateness between Viatris Inc. and Mylan Pharmaceuticals Inc., and because Mylan Laboratories Limited is a foreign entity who may be sued in any judicial district, including the District of Delaware. 28 U.S.C. § 1391(c)(3).

104. For these reasons and for other reasons that will be presented to the Court if jurisdiction or venue is challenged, the Court has personal jurisdiction over Mylan Pharmaceuticals Inc., and Viatris Inc., and venue is proper in this judicial district.

e. Nanjing Noratech Pharmaceutical Co., Limited (ANDA No. 213671)

105. This Court has personal jurisdiction over Noratech because Noratech has committed tortious acts of patent infringement in preparing and submitting ANDA No. 213671 with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which acts have led to foreseeable harm and injury to Novartis, a Delaware corporation.

106. This Court also has personal jurisdiction over Noratech because, on information and belief, Noratech, upon approval of ANDA No. 213671, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213671 that will be purposefully directed at Delaware, including the marketing of the Noratech ANDA Products in Delaware, prior to the expiration of the ’918 patent.

107. This Court also has personal jurisdiction over Noratech because, on information and belief, Noratech’s affiliations with the State of Delaware are sufficiently continuous and systematic as to render Noratech essentially at home in this forum.

108. Noratech, the entity that, on information and belief, submitted ANDA No. 213671, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213671 in the District of Delaware, and has agreed, only for the purposes of such action(s), not to challenge personal jurisdiction and venue in the District of Delaware.

109. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Noratech.

110. Venue is proper in this Court because Noratech is a foreign entity who may be sued in any judicial district, including Delaware. 28 U.S.C. § 1391(c)(3).

THE PATENT-IN-SUIT AND ENTRESTO®

111. Novartis is the owner of the '918 patent, titled "Amorphous solid form of compounds containing S-N-valeryl-N-{[2′-(1H-tetrazole-5-yl)-biphenyl-4-yl]-methyl}-valine and (2R,4S)-5-biphenyl-4-yl-4-(3-carboxy-propionylamino)-2-methyl-pentanoic acid ethyl ester moieties and sodium cations." The '918 patent was duly and legally issued on August 24, 2021. A true and correct copy of the '918 patent is attached hereto as Exhibit A.

112. The '918 patent claims, *inter alia*, an amorphous solid form of a compound comprising anionic valsartan, anionic sacubitril, and sodium cations in a 1:1:3 molar ratio.

113. Novartis is the holder of New Drug Application ("NDA") No. 207620 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of ENTRESTO® (sacubitril and valsartan) tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg. ENTRESTO® currently is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure, and for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older.

INFRINGEMENT BY EACH DEFENDANT OF THE PATENT-IN-SUIT

114. Novartis incorporates paragraphs 1 – 113 as if fully set forth herein.

a. Alembic Pharmaceuticals Limited; Alembic Global Holding SA; Alembic Pharmaceuticals, Inc. (ANDA No. 213682)

115. On information and belief, Alembic Pharmaceuticals Limited, by itself or in concert with Alembic Global Holding SA, and/or Alembic Pharmaceuticals, Inc., submitted to the FDA ANDA No. 213682 under the provisions of 21 U.S.C. § 355(j) seeking approval to

engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Alembic ANDA Products prior to the expiration of the ’918 patent.

116. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Alembic ANDA Products in or into the United States prior to the expiration of the ’918 patent, Alembic Pharmaceuticals Limited, and, on information and belief, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc., have committed an act of infringement under 35 U.S.C. § 271(e)(2).

117. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Alembic ANDA Products in or into the United States will directly infringe one or more claims of the ’918 patent.

118. On information and belief, the Alembic ANDA Products are a pharmaceutical composition in the form of a tablet comprising an amorphous solid form of a compound comprising (i) anionic valsartan, (ii) anionic sacubitril, and (iii) sodium cations in a 1:1:3 molar ratio. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Alembic ANDA Products in or into the United States will directly infringe one or more claims of the ’918 patent.

119. Novartis will be substantially and irreparably damaged by Alembic Pharmaceuticals Limited’s, Alembic Global Holding SA’s, and/or Alembic Pharmaceuticals, Inc.’s infringement of the ’918 patent.

120. Novartis is entitled to the relief provided by 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 283, including an order of this Court that the effective date of any approval of ANDA No. 213682 be a date that is no earlier than November 8, 2026, the expiration of the ’918 patent, or a

date no earlier than the expiry of any other patent extension or exclusivity to which Novartis is entitled, and an award of damages for any commercial sale or use of the Alembic ANDA Products and any act committed by Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and/or Alembic Pharmaceuticals, Inc. with respect to the subject matter claimed in the ’918 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

121. On information and belief, Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and/or Alembic Pharmaceuticals, Inc. have taken and continue to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Alembic ANDA Products, including seeking approval of those products under ANDA No. 213682.

122. There is a substantial and immediate controversy between Novartis and Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. concerning the ’918 patent. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Alembic will directly infringe one or more claims of the ’918 patent.

b. Crystal Pharmaceutical (Suzhou) Co., Ltd. (ANDA No. 213605)

123. On information and belief, Crystal submitted to the FDA ANDA No. 213605 under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Crystal ANDA Products prior to the expiration of the ’918 patent.

124. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Crystal ANDA Products in or into the United States prior to the expiration of the ’918 patent, Crystal has committed an act of infringement under 35 U.S.C. § 271(e)(2).

125. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Crystal ANDA Products in or into the United States will directly infringe one or more claims of the ’918 patent.

126. On information and belief, the Crystal ANDA Products are a pharmaceutical composition in the form of a tablet comprising (in an amount less than 10% by weight of the total amount of active ingredient in the tablet) an amorphous solid form of a compound comprising (i) anionic valsartan, (ii) anionic sacubitril, and (iii) sodium cations in a 1:1:3 molar ratio. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Crystal ANDA Products in or into the United States will directly infringe one or more claims of the ’918 patent.

127. Novartis will be substantially and irreparably damaged by Crystal’s infringement of the ’918 patent.

128. Novartis is entitled to the relief provided by 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 283, including an order of this Court that the effective date of any approval of ANDA No. 213605 be a date that is no earlier than November 8, 2026, the expiration of the ’918 patent, or a date no earlier than the expiry of any other patent extension or exclusivity to which Novartis is entitled, and an award of damages for any commercial sale or use of the Crystal ANDA Products and any act committed by Crystal with respect to the subject matter claimed in the ’918 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

129. On information and belief, Crystal has taken and continues to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Crystal ANDA Products, including seeking approval of those products under ANDA No. 213605.

130. There is a substantial and immediate controversy between Novartis and Crystal concerning the '918 patent. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Crystal will directly infringe one or more claims of the '918 patent.

c. MSN Pharmaceuticals Inc.; MSN Laboratories Private Limited; MSN Life Sciences Private Limited (ANDA No. 213748)

131. On information and belief, MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited, by themselves or in concert with MSN Life Sciences Private Limited, submitted to the FDA ANDA No. 213748 under the provisions of 21 U.S.C.§ 355(j) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the MSN ANDA Products prior to the expiration of the '918 patent.

132. By filing their ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the MSN ANDA Products in or into the United States prior to the expiration of the '918 patent, MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited, and on information and belief, MSN Life Sciences Private Limited, have committed an act of infringement under 35 U.S.C. § 271(e)(2).

133. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the MSN ANDA Products in or into the United States will directly infringe one or more claims of the '918 patent.

134. On information and belief, the MSN ANDA Products are a pharmaceutical composition in the form of a tablet comprising an amorphous solid form of a compound comprising (i) anionic valsartan, (ii) anionic sacubitril, and (iii) sodium cations in a 1:1:3 molar ratio. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or

importation of the MSN ANDA Products in or into the United States will directly infringe one or more claims of the ’918 patent.

135. Novartis will be substantially and irreparably damaged by MSN Pharmaceuticals Inc.’s, MSN Laboratories Private Limited’s, and MSN Life Sciences Private Limited’s infringement of the ’918 patent.

136. Novartis is entitled to the relief provided by 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 283, including an order of this Court that the effective date of any approval of ANDA No. 213748 be a date that is no earlier than November 8, 2026, the expiration of the ’918 patent, or a date no earlier than the expiry of any other patent extension or exclusivity to which Novartis is entitled, and an award of damages for any commercial sale or use of the MSN ANDA Products and any act committed by MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited with respect to the subject matter claimed in the ’918 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

137. On information and belief, MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited have taken and continue to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the MSN ANDA Products, including seeking approval of those products under ANDA No. 213748.

138. There is a substantial and immediate controversy between Novartis and MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited concerning the ’918 patent. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited will directly infringe one or more claims of the ’918 patent.

d. Mylan Pharmaceuticals Inc.; Mylan Laboratories Limited; Viatris Inc. (collectively, the "Mylan Defendants") (ANDA No. 213646)

139. On information and belief, Mylan Pharmaceuticals Inc., acting in concert and as a single enterprise with Viatris Inc. and acting in concert with Mylan Laboratories Limited submitted to the FDA ANDA No. 213646 under the provisions of 21 U.S.C. § 355(j), including its amendments, seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Mylan ANDA Products prior to the expiration of the '918 patent.

140. By filing their ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Mylan ANDA Products in or into the United States prior to the expiration of the '918 patent, Mylan Pharmaceuticals Inc. and, on information and belief, acting in concert and as a single enterprise with Viatris Inc., and acting in concert with Mylan Laboratories Limited have committed an act of infringement under 35 U.S.C. § 271(e)(2).

141. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Mylan ANDA Products in or into the United States will directly infringe one or more claims of the '918 patent.

142. On information and belief, the Mylan ANDA Products are a pharmaceutical composition in the form of a tablet comprising (in an amount less than 10% by weight of the total amount of active ingredient in the tablet) an amorphous solid form of a compound comprising (i) anionic valsartan, (ii) anionic sacubitril, and (iii) sodium cations in a 1:1:3 molar ratio. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Mylan ANDA Products in or into the United States will directly infringe one or more claims of the '918 patent.

143. Novartis will be substantially and irreparably damaged by the Mylan Defendants' infringement of the '918 patent.

144. Novartis is entitled to the relief provided by 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 283, including an order of this Court that the effective date of any approval of ANDA No. 213646 be a date that is no earlier than November 8, 2026, the expiration of the '918 patent, or a date no earlier than the expiry of any other patent extension or exclusivity to which Novartis is entitled, and an award of damages for any commercial sale or use of the Mylan ANDA Products and any act committed by the Mylan Defendants with respect to the subject matter claimed in the '918 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

145. On information and belief, Mylan Pharmaceuticals Inc., acting in concert and as a single enterprise with Viatris Inc. and acting in concert with Mylan Laboratories Limited have taken and continue to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Mylan ANDA Products, including seeking approval of those products under ANDA No. 213646.

146. There is a substantial and immediate controversy between Novartis and the Mylan Defendants concerning the '918 patent. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Mylan Pharmaceuticals Inc., acting in concert and as a single enterprise with Viatris Inc. and acting in concert with Mylan Laboratories Limited will directly infringe one or more claims of the '918 patent.

e. Nanjing Noratech Pharmaceutical Co., Limited (ANDA No. 213671)

147. On information and belief, Noratech submitted to the FDA ANDA No. 213671 under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial

manufacture, use, sale, offer for sale, and/or importation of the Noratech ANDA Products prior to the expiration of the '918 patent.

148. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Noratech ANDA Products in or into the United States prior to the expiration of the '918 patent, Noratech has committed an act of infringement under 35 U.S.C. § 271(e)(2).

149. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Noratech ANDA Products in or into the United States will directly infringe one or more claims of the '918 patent.

150. On information and belief, the Noratech ANDA Products are a pharmaceutical composition in the form of a tablet comprising an amorphous solid form of a compound comprising (i) anionic valsartan, (ii) anionic sacubitril, and (iii) sodium cations in a 1:1:3 molar ratio. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Noratech ANDA Products in or into the United States will directly infringe one or more claims of the '918 patent.

151. Novartis will be substantially and irreparably damaged by Noratech's infringement of the '918 patent.

152. Novartis is entitled to the relief provided by 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 283, including an order of this Court that the effective date of any approval of ANDA No. 213671 be a date that is no earlier than November 8, 2026, the expiration of the '918 patent, or a date no earlier than the expiry of any other patent extension or exclusivity to which Novartis is entitled, and an award of damages for any commercial sale or use of the Noratech ANDA

Products and any act committed by Noratech with respect to the subject matter claimed in the '918 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

153. On information and belief, Noratech has taken and continues to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Noratech ANDA Products, including seeking approval of those products under ANDA No. 213671.

154. There is a substantial and immediate controversy between Novartis and Noratech concerning the '918 patent. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Noratech will directly infringe one or more claims of the '918 patent.

PRAYER FOR RELIEF

WHEREFORE, Novartis prays that this Court grant the following relief:

a. Alembic Pharmaceuticals Limited; Alembic Global Holding SA; Alembic Pharmaceuticals, Inc.
(ANDA No. 213682)

155. Judgment that Defendants Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. have infringed one or more claims of the '918 patent by filing ANDA No. 213682;

156. A permanent injunction restraining and enjoining Defendants Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. and their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Alembic ANDA Products prior to the expiration of the '918 patent, inclusive of any extensions and additional periods of exclusivity;

157. An order that the effective date of any approval of ANDA No. 213682 be a date that is not earlier than the expiration date of the '918 patent, inclusive of any extensions and additional periods of exclusivity;

158. Declaratory judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of the Alembic ANDA Products will directly infringe one or more claims of the '918 patent;

159. Damages or other monetary relief from Defendants Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. for the direct infringement of the '918 patent;

160. A declaration that this case is an exceptional case pursuant to 35 U.S.C. § 285 and an award of attorney's fees;

161. Novartis's costs and expenses in this action; and

162. Such other and further relief as the Court may deem just and proper.

b. Crystal Pharmaceutical (Suzhou) Co., Ltd. (ANDA No. 213605)

163. Judgment that Defendant Crystal has infringed one or more claims of the '918 patent by filing ANDA No. 213605;

164. A permanent injunction restraining and enjoining Defendant Crystal and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Crystal ANDA Products prior to the expiration of the '918 patent, inclusive of any extensions and additional periods of exclusivity;

165. An order that the effective date of any approval of ANDA No. 213605 be a date that is not earlier than the expiration date of the '918 patent, inclusive of any extensions and additional periods of exclusivity;

166. Declaratory judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of the Crystal ANDA Products will directly infringe one or more claims of the '918 patent;

167. Damages or other monetary relief from Defendant Crystal for the direct infringement of the '918 patent;

168. A declaration that this case is an exceptional case pursuant to 35 U.S.C. § 285 and an award of attorney's fees;

169. Novartis's costs and expenses in this action; and

170. Such other and further relief as the Court may deem just and proper.

c. MSN Pharmaceuticals Inc.; MSN Laboratories Private Limited; MSN Life Sciences Private Limited (ANDA No. 213748)

171. Judgment that Defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited have infringed one or more claims of the '918 patent by filing ANDA No. 213748;

172. A permanent injunction restraining and enjoining Defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited and their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the MSN ANDA Products prior to the expiration of the '918 patent, inclusive of any extensions and additional periods of exclusivity;

173. An order that the effective date of any approval of ANDA No. 213748 be a date that is not earlier than the expiration date of the '918 patent, inclusive of any extensions and additional periods of exclusivity;

174. Declaratory judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of the MSN ANDA Products will directly infringe one or more claims of the '918 patent;

175. Damages or other monetary relief from Defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited for the direct infringement of the '918 patent;

176. A declaration that this case is an exceptional case pursuant to 35 U.S.C. § 285 and an award of attorney's fees;

177. Novartis's costs and expenses in this action; and

178. Such other and further relief as the Court may deem just and proper.

d. Mylan Pharmaceuticals Inc.; Mylan Laboratories Limited; Viatris Inc. (collectively, the "Mylan Defendants") (ANDA No. 213646)

179. Judgment that the Mylan Defendants have infringed one or more claims of the '918 patent by filing ANDA No. 213646;

180. A permanent injunction restraining and enjoining the Mylan Defendants and their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Mylan ANDA Products prior to the expiration of the '918 patent, inclusive of any extensions and additional periods of exclusivity;

181. An order that the effective date of any approval of ANDA No. 213646 be a date that is not earlier than the expiration date of the '918 patent, inclusive of any extensions and additional periods of exclusivity;

182. Declaratory judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of the Mylan ANDA Products will directly infringe one or more claims of the '918 patent;

183. Damages or other monetary relief from the Mylan Defendants for the direct infringement of the '918 patent;

184. A declaration that this case is an exceptional case pursuant to 35 U.S.C. § 285 and an award of attorney's fees;

185. Novartis's costs and expenses in this action; and

186. Such other and further relief as the Court may deem just and proper.

e. Nanjing Noratech Pharmaceutical Co., Limited (ANDA No. 213671)

187. Judgment that Defendant Noratech has infringed one or more claims of the '918 patent by filing ANDA No. 213671;

188. A permanent injunction restraining and enjoining Defendant Noratech, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Noratech ANDA Products prior to the expiration of the '918 patent, inclusive of any extensions and additional periods of exclusivity;

189. An order that the effective date of any approval of ANDA No. 213671 be a date that is not earlier than the expiration date of the '918 patent, inclusive of any extensions and additional periods of exclusivity;

190. Declaratory judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of the Noratech ANDA Products will directly infringe one or more claims of the ’918 patent;

191. Damages or other monetary relief from Defendant Noratech for the direct infringement of the ’918 patent;

192. A declaration that this case is an exceptional case pursuant to 35 U.S.C. § 285 and an award of attorney’s fees;

193. Novartis’s costs and expenses in this action; and

194. Such other and further relief as the Court may deem just and proper.

Dated: October 24, 2022 OF COUNSEL: Nicholas N. Kallas Christina Schwarz Christopher E. Loh Susanne L. Flanders Jared L. Stringham Shannon K. Clark Laura K. Fishwick Gregory J. Manas VENABLE LLP 1290 Avenue of the Americas New York, New York 10104 (212) 218-2100 *nkallas@venable.com* *cschwarz@venable.com* *cloh@venable.com* *slflanders@venable.com* *jlstringham@venable.com* *skclark@venable.com* *lfishwick@venable.com* *gjmanas@venable.com*	MCCARTER & ENGLISH, LLP By: /s/ Daniel M. Silver Daniel M. Silver (#4758) Alexandra M. Joyce (#6423) Renaissance Centre 405 N. King Street, 8th Floor Wilmington, Delaware 19801 (302) 984-6300 *dsilver@mccarter.com* *ajoyce@mccarter.com* *Attorneys for Plaintiff Novartis Pharmaceuticals Corporation*